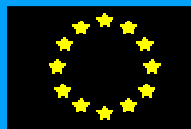


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DIMETHYL SULPHATE

CAS No: 77-78-1

EINECS No: 201-058-1

Summary Risk Assessment Report

DIMETHYL SULPHATE

CAS No: 77-78-1

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SUMMARY RISK ASSESSMENT REPORT

2002

The Netherlands

Rapporteur for the risk evaluation dimethyl sulphate is the Ministry of Housing, Spatial Planning and the Environment (VROM) in consultation with the Ministry of Social Affairs and Employment (SZW) and the Ministry of Public Health, Welfare and Sport (VWS). Responsible for the risk evaluation and subsequently for the contents of this report, is the rapporteur.

The scientific work on this report has been prepared by the Netherlands Organisation for Applied Scientific Research (TNO) and the National Institute of Public Health and the Environment (RIVM), by order of the rapporteur.

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PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance dimethyl sulphate that has been prepared by the Netherlands in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances. For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references the reader is referred to the original risk assessment report that can be obtained from the European Chemicals Bureau¹. The present summary report should preferably not be used for citation purposes.

¹ European Chemicals Bureau – Existing Chemicals – <http://ecb.jrc.it>

CONTENTS

1	GENERAL SUBSTANCE INFORMATION	3
1.1	IDENTIFICATION OF THE SUBSTANCE	3
1.2	PURITY/IMPURITIES, ADDITIVES.....	3
1.3	PHYSICO-CHEMICAL PROPERTIES	3
1.4	CLASSIFICATION	4
2	GENERAL INFORMATION ON EXPOSURE	6
3	ENVIRONMENT	7
3.1	EXPOSURE.....	7
3.1.1	PECs at production, processing, formulation and private use	7
3.1.2	Releases from other (unintentional) sources.....	7
3.1.3	Monitoring data	8
3.2	EFFECTS ASSESSMENT: HAZARD IDENTIFICATION AND DOSE (CONCENTRATION) – RESPONSE (EFFECT) ASSESSMENT.....	8
3.3	RISK CHARACTERISATION	8
4	HUMAN HEALTH	9
4.1	HUMAN HEALTH (TOXICITY).....	9
4.1.1	Exposure assessment	9
4.1.1.1	Occupational exposure	9
4.1.1.2	Consumer exposure	9
4.1.1.3	Humans exposed via the environment.....	10
4.1.2	Effects assessment	10
4.1.3	Risk Characterisation.....	11
4.1.3.1	Workers	11
4.1.3.2	Consumers	12
4.1.3.3	Humans exposed via the environment.....	12
4.2	HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES).....	12
5	RESULTS	13
5.1	ENVIRONMENT.....	13
5.2	HUMAN HEALTH.....	13

TABLES

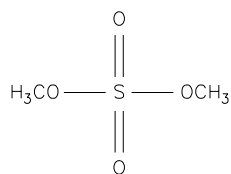
Table 1.1	Physico-chemical properties.....	4
Table 2.1	Industrial and use categories of DMS	6
Table 4.1	Inhalation and dermal exposure	9

1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS No.: 77-78-1
EINECS No.: 201-058-1
IUPAC name: dimethyl sulphate
Synonyms: DMS; methylsulphate; sulphuric acid dimethyl ester;
dimethyl monosulphate
Molecular formula: C₂H₆O₄S

Structural formula:



Molecular weight: 126.13

1.2 PURITY/IMPURITIES, ADDITIVES

Purity: >99 % w/w
Impurity: ≤0.1% w/w methanol (CAS-No. 67-56-1)
<0.5% w/w sulphuric acid (CAS-No 7664-93-9)
<0.5% w/w methyl hydrogen sulphate (CAS-No 75-93-4)
<0.5% w/w dimethyl ether (CAS-No 115-10-6)
Additives: None

1.3 PHYSICO-CHEMICAL PROPERTIES

In **Table 1.1** a list of physico-chemical properties is provided.

Table 1.1 Physico-chemical properties

Property	Result	Comment
Physical state:	liquid	*
Melting point:	~ -32°C	*
Boiling point:	188°C	*
Relative density:	1.33 at 20°C	*
Vapour pressure:	65 Pa at 20°C	***
Surface tension:	40.1 mN/cm at 18°C	**
Water solubility:	28 g/l at 20°C	**
Partition coefficient	0.16 (calc.)	**
Flammability:	not flammable	****
Flash point:	83 °C	**
Autoflammability temperature:	450 °C	**
Explosive properties:	not explosive	****
Oxidising properties:	not oxidising	****
Conversion factors (at 20 °C)	1 ppm = 5.24 mg/m ³	calculated

*More than one apparently independent source. No methods are specified

**Result of most reliable test. Other apparently independent sources provide similar results.

Most of these methods are not specified

***Different values are found in literature. The value presented in the table is considered as most appropriate

****Property based on theoretical, structural considerations

All relevant physicochemical data were provided. None of the data is based on reports, however the data are considered as sufficiently reliable to fulfil the Annex VIIA requirements.

1.4 CLASSIFICATION

Classification and labelling according to the 26th ATP of Directive 67/548/EEC²:

Classification:	Carc. Cat. 2; R45 Muta. Cat. 3; R68 ³ T+; R26 T; R25 C; R34 R43	May cause cancer. Possible risk of irreversible effects. Very toxic by inhalation. Toxic if swallowed. Causes burns. May cause sensitisation by skin contact.
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Labelling:	T+ R: 45-25-26-34-43	S: 53-45
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² The classification of the substance is established by Commission Directive 2001/32/EC of 19 May 2000 adapting to technical progress for the 26th time Council Directive 67/548 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 136, 8.6.2000, p.1).

³ The entries were amended by replacing 'Muta.Cat. 3; R40' to 'Muta. Cat. R68' according to the Commission Directive 2001/59/EC of 6 August 2001 adapting to the technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 225, 21.8.2001, p.1).

Specific concentration limits:

$C \geq 25\%$:	T+; R45-25-26-34-43
$10\% \leq C < 25\%$:	T+; R45-22-26-34-43
$7\% \leq C < 10\%$:	T+; R45-22-26-36/37/38-43
$5\% \leq C < 7\%$:	T; R45-22-23-36/37/38-43
$3\% \leq C < 5\%$:	T; R45-22-23-43
$1\% \leq C < 3\%$:	T; R45-23-43
$0,1\% \leq C < 1\%$:	T; R45-20
$0,01\% \leq C < 0,1\%$:	T; R45

2

GENERAL INFORMATION ON EXPOSURE

The production of dimethyl sulphate (hereafter referred to as DMS) at tonnages of >1,000 tpa is located at three sites in the European Union. The total EU production volume for 1994 was estimated to be between 20,000 and 30,000 tpa. An amount of 5,000-10,000 tpa is exported (outside EU) and a small quantity of <1,000 tpa is imported. About 20,000 tpa is industrially used within the EU.

The production and transferral of DMS takes place in a closed continuous system. Liquid SO₃ is added to gaseous dimethylether in a reaction vessel, containing about 97% DMS, sulphuric acid and monomethyl sulphate which are continuously withdrawn and purified by vacuum distillation over sodium sulphate. The reaction system has an underpressure to avoid leakages of DMS.

Table 2.1 shows the industrial and use categories of DMS for the European market.

Table 2.1 Industrial and use categories of DMS

Industrial category	EC no.	Use category	EC no.	Main category
Chemical industry: used in synthesis	3	Intermediates	33	I b Intermediates stored on site I c Intermediate stored off site

DMS is mainly used as a chemical intermediate. Its major applications are as a methylating agent of many organic chemicals (e.g. amines, carbon acids, thiols and phenols) both in industry and laboratories. DMS is for example used in the manufacturing of dyes, perfumes, pharmaceuticals, for the separation of mineral oils, and for the analysis of automobile fluids. The substance has also sulphating properties with applications in the manufacturing of various products (e.g. dyes and fabric softeners etc.). Formerly, DMS was used as a war gas.

3 ENVIRONMENT

3.1 EXPOSURE

DMS may enter the environment during its production and industrial use (processing), and in emissions from power plants that are burning sulphur-containing coal/fuel.

General characteristics of DMS that are relevant for the exposure assessment are: an estimated atmospheric half-life of 84 days for the reaction with photochemically produced hydroxyl radicals, a fast hydrolysis rate in water ($DT_{50} < 1$ day), readily biodegradable, a relatively low Henry constant of $0.39 \text{ Pa}\cdot\text{m}^3/\text{mol}$ indicating that the compound shows no tendency to evaporate from water and a relatively low $\log K_{ow}$, of 0.16. From the $\log K_{ow}$, a $\log K_{oc}$ of 1.38 is calculated indicating that DMS has a low adsorption potential and thus a high mobility/leaching potential. On the basis of the high water solubility, the hydrolysis rate of DMS and the low calculated $\log K_{ow}$ of 0.16, no bioaccumulation of DMS is expected.

3.1.1 PECs at production, processing, formulation and private use

Water

All EU production and large (>1,000 tpa) processing sites of DMS submitted site specific information on the aquatic releases of the substance DMS. At these production and processing sites there is no emission to waste water due to treatment of wastewater with alkaline baths and incineration of waste products. For this reason no predicted environmental concentrations (PECs) in water were calculated for DMS itself.

DMS is known to hydrolyse very rapidly into monomethylsulphate and methanol. Thus it is considered also relevant to focus the risk assessment on the hydrolysis products, in particular monomethylsulphate (and sulphate). Local PECs are calculated for these DMS hydrolysis products for a number of production and processing sites (large and smaller ones). This was done according to the TGD and using both default emission rates and site-specific information on tonnages and river flows.

Air

Exhaust gases after production and processing are treated with alkaline baths. Therefore emissions to air are, theoretically, assumed to be zero. Four companies submitted measured or calculated release data of DMS to air. Three of them indicated that measured levels are found to be below the detection limits. For one site, however, an estimated air release figure of 35 g/a is reported and this value was used in this exposure assessment. With the OPS-model (EUSES) a local PEC of $32 \text{ pg}/\text{m}^3$ in air was calculated.

3.1.2 Releases from other (unintentional) sources

The reaction of SO_2 with organic compounds in the atmosphere and combustion of fossil-containing fuels may result in the formation of a variety of compounds including DMS and monomethyl sulphuric acid. There are no release data available from these sources. For monitoring data: see Section 3.1.3.

3.1.3 Monitoring data

There are no measured environmental concentrations available for any of the DMS production and/or processing sites. However, a number of measured concentrations of DMS in air in the vicinity of coal or oil-fired heating plants have been reported. Taking into account both the large uncertainty of the calculated local DMS concentration of 32 $\mu\text{g}/\text{m}^3$ (see paragraph 3.1.1) and the unknown representativity of the monitoring data, it can nevertheless (prudently) be concluded that 1) DMS may occur in our atmospheric environment (more actual monitoring data are needed), but that 2) the contribution of DMS emissions from production/processing sites will be very low compared to those from unintentional sources.

3.2 EFFECTS ASSESSMENT: HAZARD IDENTIFICATION AND DOSE (CONCENTRATION) – RESPONSE (EFFECT) ASSESSMENT

Short-term toxicity data are available for fish, daphnia and algae. The PNEC for the aquatic compartment is extrapolated from the lowest short-term toxicity result, i.e. 14 mg/l for the goldfish, using an extrapolation factor of 1000. This results in a PNEC of 14 $\mu\text{g}/\text{l}$.

Since risk assessment is carried out also for the hydrolysis products of DMS, i.e. sulphate and monomethylsulphate, PNECs are derived for these substances as well. An estimate of the PNEC of monomethylsulphate is obtained from one toxicity value and is set at 10 mg/l. As a rather worst-case PNEC for sodium sulphate, a value of 630 $\mu\text{g}/\text{l}$ is chosen.

The PNEC of DMS for microorganisms in a Sewage Treatment Plant (STP) is extrapolated from the activated sludge test result, i.e. an EC_{50} of 377 mg/l, using an extrapolation factor of 100. This results in a PNEC of 3.8 mg/l. The PNEC for the terrestrial compartment was estimated from the PNEC for aquatic organisms using the equilibrium partitioning method (TGD). This results in a $\text{PNEC}_{\text{terrestrial}}$ of 2 $\mu\text{g}/\text{kg}$.

3.3 RISK CHARACTERISATION

The environmental risk characterisation, i.e. the comparison of the PECs with the corresponding PNECs, revealed that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied (**conclusion ii**). This conclusion applies to both DMS and its hydrolysis products.

4 HUMAN HEALTH

4.1 HUMAN HEALTH (TOXICITY)

4.1.1 Exposure assessment

4.1.1.1 Occupational exposure

DMS is produced and used in closed systems in the chemical industry, where it is used as an intermediate. Strict technical control measures are in place to minimise exposure, because the hazardous properties of DMS have generally been recognised. Workers may be exposed to DMS, mainly due to transferral of the substance from one system into another, e.g. during filling or emptying of tankers and drums.

Several sets of measured exposure data were available. Also, the EASE model was used to estimate exposure for use in closed systems. Typical full-shift exposure levels in production of DMS are in the order of 0.01 mg/m³, while reasonable worst-case full-shift exposure levels are up to 0.05 mg/m³. For use of DMS as an intermediate, the typical full-shift exposure levels are in the order of 0.04 mg/m³, with reasonable worst-case full-shift exposure levels of up to 0.2 mg/m³. For both scenarios short-term (peak) exposure levels of up to 5 mg/m³ are considered possible.

Dermal exposure only occurs accidentally in situations where the strict control measures fail.

Table 4.1 Inhalation and dermal exposure

Scenario	Exposure		Estimated inhalation exposure level (mg/m ³)						Estimated skin exposure level (mg/day)
	Duration (hr/day)	Frequency (days/year)	Long term				Short term		
			Typical		Reasonable worst case				
			Level	Method	Level	Method	Level	Method	
1. Production <i>Breaching of closed system</i>	6-8 <1	100-200 100-200	0.01	Lit.	0.05	EASE, Lit.	5	Lit., EASE	only accidental exposure
2. Use as an intermediate <i>Breaching of closed system</i>	6-8 <1	100-200 100-200	0.04	Lit.	0.2	Lit.	5	Lit., EASE	only accidental exposure

Lit = mainly based on measured data

EASE = based on EASE, taking account of measured data

4.1.1.2 Consumer exposure

Exposure to DMS in consumer products is considered to be negligible.

4.1.1.3 Humans exposed via the environment

Humans may be exposed to DMS from industrial emissions (at production and processing) and from other (unintentional) sources, due to reaction of SO₂ with organic compounds and combustion of fossil containing fuels. Emissions to water of DMS do not occur. For one of the production sites a PEC_{air} of 32 pg/m³ has been calculated, for the other sites emissions to air are assumed to be zero (closed systems). Some monitoring data are available for unintentional sources, which indicate that industrial emissions are low compared to those from unintentional sources. However, the monitoring data are outdated and the representativity/validity is questionable.

Regional concentrations of DMS are considered to be negligible. Therefore, no risk characterisation is carried out for the regional scenario.

4.1.2 Effects assessment

DMS is a methylating agent, which is found to react with nucleic acids. No data on interference with other nucleophilic macromolecules, e.g. proteins, were provided.

Data on dermal absorption are limited and insufficient to draw conclusions. DMS can be absorbed via respiratory and oral routes. For oral absorption this is concluded from toxicodynamic data. Rapid respiratory absorption is observed in rats exposed to dose levels up to 50.3 mg/m³. At higher dose levels uptake was decreased, probably due to a decreased minute volume. No information is provided on the metabolism of DMS in animals following oral administration. The information on metabolism after inhalatory or dermal exposure is limited. DMS may be hydrolysed to methanol, sulphuric acid, and methyl sulphate, and may be metabolised to a lesser extent to formaldehyde and formate.

The toxicokinetic studies do not allow derivation of quantitative figures on absorption that can be used in risk characterisation.

The available acute toxicity data indicates that, according to EU-criteria, DMS is toxic after oral administration, and very toxic after exposure by inhalation.

DMS is corrosive to the skin and should be considered to cause risk of serious damage to eyes in laboratory animals. Irritation of the respiratory tract was observed in a poorly reported inhalation experiment with rats.

Local effects of DMS after dermal and respiratory exposure have also been seen in humans.

Based on the results of the local lymph node assay, it is concluded that DMS has sensitising properties.

The repeated dose inhalation studies do not permit the establishment of a NOAEL. No oral or dermal repeated dose toxicity studies are available. The data submitted do not fulfil the basic requirements as specified in Annex VIIA of Directive 67/548/EC.

DMS is a potent direct-acting genotoxicant in bacteria and mammalian cells *in vitro*. It is positive in tests for primary DNA damage, gene mutations, and chromosome aberrations *in vitro*. DMS appears genotoxic in various *in vivo* tests in *Drosophila*, i.e., in tests for somatic mutations and recombination, for sex-linked recessive lethals, and for sex chromosome loss. From the results of the tests with mammals it is concluded that DMS may have clastogenic activity in

somatic cells *in vivo*, but there are no indications for the induction of gene mutations *in vivo*. No tests are available to assess the genotoxicity of DMS in germ cells in mammals.

Evidence on human carcinogenicity is inadequate. The conclusion of IARC is that DMS produces mainly local tumours in rats following inhalation or subcutaneous injection and that there is sufficient evidence to classify DMS as an animal carcinogen (2A). This conclusion is in agreement with the conclusion of this risk assessment. IARC's statement on tumours of the nervous system after prenatal exposure of laboratory animals could not be verified. Given the results of the mutagenicity studies, it is assumed that the carcinogenicity of DMS is based on a genotoxic mode of action.

The study design of the carcinogenicity study of Schlögel does not fulfil the requirements of test guideline OECD 451. However, the results of this study can be used to give an indication of the carcinogenic potency of DMS.

The toxicological database of DMS has gaps with respect to systemic toxicity after repeated exposure, and with respect to effects on reproduction. There are no data available on toxicological parameters such as haematology and clinical chemistry. Furthermore, no data are available on fertility effects of DMS.

It is concluded that DMS only induced slight developmental toxicity after inhalation at maternally toxic concentrations. In order to investigate the potential reproductive toxicity of DMS, at least investigation of reproductive organs in a 90-day repeated dose toxicity test or preferably, a study, should have been performed.

4.1.3 Risk Characterisation

4.1.3.1 Workers

Despite the effects observed in the acute toxicity studies and the skin and eye irritation studies, there is no concern for workers with regard to these effects, because of the anticipated exposure levels and the protective effects of PPE (**conclusion ii**). The effects observed in the sensitisation study do not point to concern for this endpoint (**conclusion ii**).

Based on the MOS between the NOAEL for nasal irritation in rats (0.5 mg/m³) and the anticipated inhalation exposure levels (0.05-0.2 mg/m³) it is concluded that there is concern for workers with regard to this endpoint, and the remaining risk for workers using typical PPE properly may still be substantial in this situation, given the MOS for the unprotected worker and the indicative value for protective effect of the PPE (**conclusion iii**).

From the results of the mutagenicity studies it is concluded that DMS is a category 3 mutagen and category 2 carcinogen. Therefore, control measures to limit the risks for the workers are needed, which should be in accordance with European legislation regarding worker protection (**conclusion iii**).

Because DMS is classified as a genotoxic carcinogen, there is concern for workers. Despite the limitations on the carcinogenicity study available, a T25 of 0.05 mg/kg bw/d is calculated. The cancer risks for the scenario 'production' and the scenario "use as intermediate" are $4.4 \cdot 10^{-3}$ and $0.8 \cdot 10^{-1}$, respectively, using linear extrapolation and dose-correction to occupational exposure conditions. Therefore, it is concluded that occupational exposure gives considerable concern (**conclusion iii**).

Based on the MOS (2.5) between the NOAEL (0.5 mg/m³) for maternal toxicity observed in the inhalatory developmental study and the anticipated inhalation occupational exposure levels in the scenario ‘use as intermediate’ (0.05-0.2 mg/m³) it is concluded that health risks for pregnant workers cannot be excluded (**conclusion iii**), but are unlikely to occur in this population exposed during ‘production’ (MOS of 10). The data available do not allow a definite conclusion on reproductive effects after dermal exposure, because studies on these parameters tested via the dermal route were not available. However, the risk for reproductive effects after occupational dermal exposure is considered to be low, because (1) DMS is very reactive and will bind primarily to the application site, and (2) developmental effects in the inhalation developmental study occurred only at clear-cut maternally toxic concentrations, and (3) the dermal exposure is limited to accidental events (**conclusion ii**).

In principal, additional studies resulting in a NOAEL for systemic effects after repeated dosing are needed for quantitative risk characterisation, as no reliable repeated-dose studies were provided and exposure to DMS at the workplace cannot be excluded. Furthermore, there are no data on effects on fertility. However, it is noted that the carcinogenic activity of DMS, i.e., the cancer incidence per mg/m³ under occupational conditions of exposure, points to very low acceptable exposure levels with regard to the carcinogenic effects. It is expected that compliance to these low exposure levels will prevent effects other than carcinogenic effects to occur.

4.1.3.2 Consumers

Consumer exposure to DMS is considered to be negligible. DMS is an animal carcinogen and the carcinogenicity of DMS is based on a genotoxic mechanism (**conclusion iii**). However, since consumer exposure is considered negligible, the risk will also be negligible.

4.1.3.3 Humans exposed via the environment

DMS emissions from production/processing sites are rather low (calculated concentration in air for one site 32 pg/m³). Much higher DMS emissions may occur from unintentional sources.

DMS is an animal carcinogen and the carcinogenicity of DMS is based on a genotoxic mechanism. However, since industrial emissions are rather low, the risk is probably residual.

Taking into account the nature of the substance (being a genotoxic carcinogen), more information on actual release figures and/or concentrations from combustion processes (unintentional sources) are needed.

4.2 HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES)

Given the physico-chemical data, DMS is considered not to form a risk with respect to flammability, explosive properties, and oxidising properties (**conclusion ii**).

5 RESULTS

5.1 ENVIRONMENT

- i) There is need for further information and/or testing.
- ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied.
- iii) There is a need for limiting the risks: risk reduction measures which are already being applied shall be taken into account.

5.2 HUMAN HEALTH

Human health (toxicity)

Workers

- i) There is need for further information and/or testing.
- ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied.
- iii) There is a need for limiting the risks: risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) is reached because of:

- concerns for risks for respiratory tract irritation, mutagenicity, and carcinogenicity as a consequence of inhalation exposure arising from production, processing and use of the substance;
- concerns for the pregnant population for additional adverse health effects as a consequence of repeated inhalation exposure arising from the use of the substance as an intermediate.

It is noted that the toxicological database of DMS has gaps with respect to systemic toxicity after repeated exposure, and with respect to effects on reproduction. Furthermore, the carcinogenicity study of Schlögel has serious limitations. However, it is noted that the carcinogenic activity of DMS, i.e., the cancer incidence per mg/m³ under occupational conditions of exposure, points to very low acceptable exposure levels with regard to the carcinogenic effects. It is expected that compliance to these low exposure levels will prevent effects other than carcinogenic effects to occur.

Consumers

- i) There is need for further information and/or testing.
- ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied.
- iii) There is a need for limiting the risks: risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) is reached because of:

- the risk assessment shows that risks cannot be excluded at any exposure as the substance is

identified as a non-threshold carcinogen. However, the risks covered by this risk assessment are not of a magnitude, that immediate action is deemed necessary. Risk reduction measures already being applied are considered sufficient to impose pressure in reducing and controlling exposure to the substance.

Humans exposed via the environment (industrial emissions)

- i)** There is need for further information and/or testing.
- ii)** There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied.
- iii)** There is a need for limiting the risks: risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) is reached because of:

- the risk assessment shows that risks cannot be excluded at any exposure as the substance is identified as a non-threshold carcinogen. However, the risks covered by this risk assessment are not of a magnitude, that immediate action is deemed necessary. Risk reduction measures already being applied are considered sufficient to impose pressure in reducing and controlling exposure to the substance.

In addition to the conclusions according to Council Reg. 793/93/EEC given above, the RAR came to the conclusion concerning emissions from unintentional sources as follows:

Indirect exposure via the environment (unintentional sources)

- i)** There is need for further information and/or testing
- ii)** There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied
- iii)** There is a need for limiting the risks: risk reduction measures which are already being applied shall be taken into account

Conclusion (i) is reached because:

- more information is needed about actual atmospheric concentrations of DMS from unintentional sources. Such data are important to make an up-to-date exposure assessment for this compound, being with a genotoxic carcinogen.

Human health (physico-chemical properties)

Given the physico-chemical data, DMS is considered not to form a risk with respect to flammability, explosive properties, and oxidising properties (**conclusion ii**).

